

### The rejection for obviousness type double patenting

Claims 1-15 were rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-5 and 20 of U.S. Patent No. 7,344,710 in view of Fojo, Helson, and Dewhirst. Although not rejected in the final rejection, claims 25 and 26 appear to have been newly rejected in the Advisory Action.

Each of these claims had been previously rejected for statutory obviousness under § 103 using the same references. The arguments which were presented in the prior response, which argued unexpected results and a teaching away in the prior art, were found persuasive. The rejection under § 103 was withdrawn.

Claims 1-5 and 20 of U.S. Patent No. 7,344,710 ('710) are directed to methods of treating a tumor in which Clostridium spores are administered or in which Clostridium spores are administered and an antitumor agent is administered. Fojo teaches the use of microtubule stabilizing agents as anti-tumor agents. See Figure 2 and the first paragraph on page 294. The rejection asserts that one of skill in the art would have been motivated based on the '710 claims to administer Clostridium spores and microtubule stabilizing agents as recited in the rejected claims.

The MPEP provides guidance on the requirements of a double patenting rejection (§ 804.II): "Domination and double patenting should not be confused. They are two separate issues. One patent or application 'dominates' a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application. Domination by itself, *i.e.*, in the absence of statutory or non-statutory double patenting grounds, cannot support a double patenting rejection. *In re Kaplan*, 789 F.2d 1574, 1577-78, 229 USPQ 678, 681 (Fed. Cir. 1986); and *In re Sarrett*, 327 F.2d 1005, 1014-15, 140 USPQ 474, 482 (CCPA 1964)."

The MPEP, in discussing *In re Kaplan*, states that "the mere fact that the broad process claim of the patent requiring an organic solvent reads on or 'dominates' the narrower claim directed to basically the same process using a specific solvent mixture does not, *per se*, justify a double patenting rejection." § 804.B.2.

As a preliminary matter, the subject claims are not directed to the same invention as in the '710 claims. The same invention means identical subject matter. Even claim 3 of the '710

patent which specifies the administration of an anti-tumor agent generically, does not teach the same invention as the rejected claims which each specify administration of a microtubule stabilizing, anti-tumor agent. Since many anti-tumor agents could be used without literally infringing the rejected claims, statutory double patenting would not be appropriate. See MPEP § 804.II.A.

For non-statutory double patenting, the MPEP guides us: the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a **35 U.S.C. 103(a)** rejection, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under **35 U.S.C. 103** are employed when making an obvious-type double patenting analysis. These factual inquiries are summarized as follows:

- (a) determine the scope and content of a patent claim relative to a claim in the application at issue;
- (b) determine the differences between the scope and content of the patent claim as determined in (a) and the claim in the application at issue;
- (c) determine the level of ordinary skill in the pertinent art; and
- (d) evaluate any objective indicia of non-obviousness.

Applicants request that the U.S. Patent and Trademark Office consider the objective indicia of non-obviousness which were presented with regard to the statutory rejection under § 103. However, because those objective indicia included some teachings from the ‘710 specification, and because the U.S. Patent and Trademark Office is reluctant to use the specification for any purpose in the context of a non-obviousness double patenting rejection, applicants ask that the U.S. Patent and Trademark Office consider the teachings of the Dang et al. publication, *Proc. Nat’l. Acad. Sciences*, 98, 15155-15160, 2001. This reference is already of record in this application and the examiner has considered it.<sup>1</sup> This reference forms part of the state of the art and thus is relevant under factor (d) above. This reference contains essentially the same teachings and data as are in the ‘710 patent.

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<sup>1</sup> The reference is erroneously listed, however under the first name of Dr. Long Dang, as D. Long et al.

The Dang reference teaches that a beneficial combination of drug with spores would be one that collapses or *destabilizes* microtubules. See page 15158, sentence spanning columns 1 and 2. Dang not only teaches the use of such drugs, but provides a rationale for using such drugs. “The latter class of agents [that appear to partially collapse tumor vasculature, such as flavone acetic acid derivatives and microtubule binding agents] has been shown to be able to interfere with proper circulation through the tumors and thereby trap large molecules, such as antibodies or bacteria, that have gained access to the tumor tissue (Theys, 2001)(Pedley, 1999)(Pedley, 2001).” Dang at page 15158, column 2, first sentence. Dang further explained: “Presumably, the vascular collapse further lowered the oxygen tension near the trapped bacteria and thereby increased the potential for bacterial growth.” Dang at page 15159, column 2, last paragraph. Thus Dang teaches that one should use microtubule *destabilizing* agents in combination with the bacterial spores in order to trap the bacteria in the tumors. This is an implicit *teaching away* from combining spores with agents that would have the diametrically opposite effect.

The unexpected results taught in the subject application and discussed with regard to the § 103 rejection must also be considered. First, the specification teaches the unexpected potency of the combination of spores and microtubule stabilizing agents. The agents alone led to a *transient* tumor regression, but the addition of spores led to *cures*. Second, unexpectedly, the combination of microtubule stabilizing agents and spores as claimed in the subject application is less toxic than the prior art combination of microtubule destabilizing agents and spores. These teachings are secondary considerations that rebut the obviousness-type double patenting rejection.

Applicants request that the single remaining rejection be withdrawn.

Respectfully submitted,

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